Advisory Action Before the Filing of an Appeal Brief	**Application No.** 10/519,715	**Applicant(s)** WANNERBERGER ET AL.	
	Examiner Jeffrey T. Palenik	**Art Unit** 1615	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 11 August 2010 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☒ The period for reply expires *6* months from the mailing date of the final rejection.
   b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: _____.
   Claim(s) objected to: _____.
   Claim(s) rejected: *1,3,4,6,7 and 13-18*.
   Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
12. ☐ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). _____
13. ☐ Other: _____.

/Jeffrey T. Palenik/
Examiner, Art Unit 1615

/Robert A. Wax/
Supervisory Patent Examiner, Art Unit 1615

Continuation of 11. does NOT place the application in condition for allowance because: The Examiner, on consideration of Applicants' instantly amended base claim, understands that the composition recites a narrower structural scope to the previously recited tablet wherein components: A.) desmopressin or one of its pharmaceutically active salts, B.) an acid providing a pH of 3.0-6.2 upon contact with water, and C.) a pharmaceutically active adjuvant, diluent or carrier (herein, collectively referred to as components "A-C") are all within the granules which are then compressed to form the resulting tablet. Comparatively, the previously claimed dosage form is a compressed tablet of granulates simply comprising components "A" through "C".

Reconsideration of the amended limitations in light of the teachings of Fein will result in the entrance of the claims filed 21 July 2010. However, the amendments to the limitations are not considered to be persuasive in overcoming the outstanding obviousness rejection made over Fein. In particular, the Fein reference teaches a hard, compressed tablet form, which includes prepared particles comprising the active ingredient (e.g., desmopressin acetate) as well as a "protective" material [0040]. This "particle" teaching is considered by the Examiner as a teaching which conveys the structural equivalent of a granule (e.g., a pellet, granule, particle, particulate, etc.), absent a clear showing of evidence to the contrary. In light of the instantly claimed "granule" containing "A"-"C" versus the particle which contains the active and a protective material, the structural similarities (i.e., combination of multiple components in a single compressible entity) leads the Examiner to consider Fein's teaching as being consistent with that of a granule, as instantly claimed.

The composition is further disclosed as containing an "effervescent couple" which is further taught as comprising such acids as citric, tartaric, malic and adipic acids [0052]. Concerning the acids which are taught (e.g., citric), properties which are known, such as its ability to function as a pH-adjusting agent as well as the pH ranges in conveys, are clearly disclosed by the reference as well [0091].

Where the Fein reference is apparently distinct from the art of record is that the acid (e.g., component "B") stands apart from the particle structure of Fein, whereas the instant claims recite that it is combined with the granules.

Despite the amendment to the claims, the Examiner continues to consider the Fein reference as disclosing an obvious variation to the instantly claimed tablet.

Applicants' arguments pertaining to the means through which the tablets are prepared have been considered but respectfully are not persuasive. Initially, the Examiner does understand the technology of granulation as being the combination and sieving of reagents in order to form granules or particles of multiple components. As the instant invention is drawn to a composition such method limitations are considered as being product-by-process limitations (MPEP §2113). Concerning the teachings of the reference, as discussed above, Fein discloses the hard compression of particles (e.g., active and protective excipient) into a final tablet form.

Applicants' further allege that Fein does not teach a compressed granulate comprising desmopressin and an acid on the grounds that "[s]lurrying such a tablet [per Fein] would promote reaction between the acid and effervescent agent, resulting in consumption of the acid, not the provision of the desired pH".

The Examiner respectfully maintains that whether the acid is found within the granulates or within the body of the tablet, per Fein, on exposure to the oral cavity or water, said acid will be released and will convey its acidity to its surrounding environment, in essence adjusting the pH of its environment. That being said, the dosage forms of Fein do comprise both desmopressin and an acid, albeit using a structural combination which would have been obvious to the person of ordinary skill in the pharmaceutical arts, absent a clear showing of evidence to the contrary.

Concerning Applicants' allegations that Fein does not teach packaging a desmopressin tablet in blister packs, the Examiner respectfully points to the Examples which expressly disclose the packaging of the freeze-dried formulation using a blister laminate comprising PVC coated with PVdC (e.g., Ex. 1). Considering the other dosage forms disclosed within the reference (i.e., compressed hard tablets at [0040]) it stands to reason that it would have been well within the purview of the ordinarily skilled artisan to package such tablets in a similar fashion, absent a showing of evidence to the contrary.

For these reasons, Applicants' arguments are found unpersuasive. Said rejection is therefore maintained and extended to include newly added claim 18, which is directed to limiting the desmopressin active ingredient to the species of desmopressin acetate. Fein expressly discloses in [0029] that the acetate salt form of desmopressin is particularly preferred.